



Our Ref. No.: 003764.P002

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:

**Pinaki Ray**

Application No.: **09/475,768**

Filed: **December 30, 1999**

For: **CONDUIT SYSTEM FOR ISOLATION OF  
FLUIDS IN BIOLOGICAL TISSUES**

Examiner: **Williams, Catherine Serke**

Art Unit: **3763**

Confirmation No.: **6849**

**REPLY BRIEF**

Mail Stop Appeal Brief - Patent  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In response to the Examiner's Answer mailed November 25, 2005, Applicant submits the following Reply Brief.

A. Rejection of Claims 1-9, 12-13 & 48-60 as Obvious Over Boddie in view of Aigner

The Patent Office rejects claims 1-9, 12-13 and 48-60 under 35 U.S.C. §103 as obvious over Boddie over Aigner. The Patent Office relies on this combination to reject the noted claims by arguing among other things that a description of the external accessibility of channels of a patient in the claims is readable on an open chest cavity procedure; and there is a motivation to combine Aigner with Boddie, because Boddie notes that in certain instances, ligatures around a point of a splint catheter are difficult and a balloon prevents undue organ damage. Applicant offers the following analysis of each of these points.

### 1. Externally Accessible

The Patent Office admits in its Examiner's Answer that Boddie and Aigner each teach open chest cavity procedures. The Patent Office argues that Boddie teaches external accessibility of a channel despite its teaching of an open chest cavity procedure. The Patent Office cites *The American Heritage® Dictionary of the English Language, Fourth Edition* for a definition of "externally" and "accessible." According to the definition of externally, the definition includes:

1. Relating to, existing on, or connected with the outside or an outer part; exterior.

Femoral arteries, radial arteries and jugular arteries all meet this definition in that they relate to or exist on an outside part of the human body. Albeit, each artery is beneath the skin, the artery still relates to the external portion of a patient's body. Quite the contrary, a hepatic artery, a hepatic vein, a portal vein, the inferior vena cava, etc. as described in Boddie are not external in terms of the definition provided by the Patent Office. Only by opening the chest cavity does Boddie teach accessing these vessels.

With respect to the definition of "accessible," *The American Heritage® Dictionary of the English Language, Fourth Edition* includes:

1. Easily approached or entered.

Relatively speaking, a percutaneous access via a radial artery, a femoral artery, or a jugular vein is easily approached or entered relative to, for example, an open chest cavity procedure. Only by ignoring the arduous task of opening the chest cavity may a hepatic artery or vein, or a portal vein be considered easily approached or entered according to Boddie and Aigner. It is a strain on the definition and the claim language to ignore the opening of a chest cavity in the context of determining whether a delivery conduit or a collection conduit has a length measured from an externally accessible channel of a patient.

## *2. No Motivation to Combine the Teachings of Aigner with Boddie*

The Patent Office argues that Aigner provides motivation to modify the ligatures of Boddie within an occlusion balloon because positioning ligatures around vessels can present a problem by potentially damaging surrounding organs and an occlusive balloon solve this problem.

In the Appeal Brief, Applicant argued that, upon its understanding Boddie, Boddie utilizes several ligatures primarily to conformably engage and releasably hold catheters to arteries or veins, not to block them. Accordingly, substituting a balloon for any of these ligatures would not be suitable. Applicant also pointed out that Boddie does teach one ligature used to occlude the hepatic artery to prevent blood flow into the liver. See col. 3, lines 40-42. This ligature is associated with a delivery conduit as identified by the Patent Office, not a collection conduit. Applicant pointed out that, in its understanding of Boddie, to substitute a balloon for the ligature preferred by Boddie, one presumably would have to branch first branch catheter 35 in a direction downstream (towards the liver) and a position upstream. This separate branching of first branch catheter 35 is not taught by Boddie. Nevertheless, one must read into Boddie presumably that the upstream-directed branch would contain the balloon catheter portion. These presumptions are not taught anywhere in Boddie or Aigner. Applicant also noted that even if a balloon catheter was utilized as Applicant (not Boddie or Aigner) has described, a ligature would still likely be necessary to stop blood flow while the branch device is placed. In such case, a ligature would be necessary. Therefore, there is no reason for a balloon and there is no benefit for utilizing a balloon since a ligature is still necessary. In other words, a balloon and a ligature does not necessarily prevent the potential problem noted by the Patent Office by the use of ligatures around a vessel, since the ligature would arguably still be necessary.

The Patent Office equates catheter 41 of Boddie as a collection conduit. According to Applicant's understanding of Boddie, however, catheter 41 does not collect a fluid but instead routes blood flowing from the hepatic artery to the heart. At best, tube 61 might qualify as a collection conduit. "[I]f one follows the route of the blood flow that is designated by single-headed arrows in FIG. 3 (i.e., the blood that is flowing in the general circulatory system), and compares it with the route of the blood flow that is designated by double-headed arrows in

FIG. 3 (i.e., the blood flow that is limited to and from the cancer-involved liver by the use of my invention), then one can readily see how my invention structurally and successfully accomplishes the function of selectively isolating the liver's blood circulation from the blood circulation of the rest of the body. . . ." Col. 3, lines 53-55. According to this description, Figure 3 shows first catheter 41 routing blood from the hepatic artery to the heart. Tube 61 extends through catheter 41 and presumably into the hepatic vein to collect fluid (blood) from the liver. Tube 61 is not engaged or releasably held to a blood vessel by a ligature. Instead, tube 61 is positioned through catheter 41 and presumably engaged or releasably held by catheter 41, not a ligature. Boddie solves the alleged motivation of minimizing damage surrounding organs by routing tube 61 through another catheter. Thus, a need for a ligature or a balloon is avoided. In other words, there would be no motivation to associate a balloon with tube 61 particularly where Boddie describes routing tube 61 through catheter 41.

For the above stated reasons, claim 1 is not obvious over the cited references. Claims 2-9 and 12-13 depend from claim 1 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 1, claims 2-9 are not obvious over the cited references.

Independent claim 48 describes a delivery conduit and a collection conduit comprising a collection seal for occluding fluid flow by the collection seal. Each of the delivery conduit and the collection conduit has a length dimension suitable to be positioned by a percutaneous transluminal route from an externally accessible channel of a patient.

Claim 48 is not obvious over the cited references for the reasons noted above with respect to claim 1. Namely, neither Boddie nor Aigner describe a length dimension of a delivery conduit and a collection conduit suitable to be positioned by percutaneous transluminal routes from externally accessible channels. Further, as noted above with respect to claim 1, there is no motivation to combine Boddie and Aigner, because Boddie does not need a ligature or balloon on tube 61, the conduit identified as a collection conduit in the reference made by the Patent Office or to be used as an occlusion device, it does not appear practical or even feasible to occlude a hepatic artery.

Claims 49-60 depend from claim 48 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 48, claims 49-60 are not obvious over the cited references.

Applicant respectfully requests the Patent Office withdraw the rejection to claims 1-9, 12-13 and 48-60 under 35 U.S.C. §103(a).

**B. Rejection of Claims 10-11 as Obvious Over Boddie**

Claims 10-11 are rejected as obvious over Boddie in view of Aigner. The Patent Office believes the claims recite functional aspects. Applicant respectfully disagree. By specifying a biological mass as a human heart (claim 10), a length dimension of a delivery conduit and a collection conduit are further specified. This is not a functional aspect but contributes to a structural interpretation of structural elements of claim 1.

Similarly, claim 11 provides a structural limitation to the delivery conduit by giving it a size (e.g., an exterior diameter).

The combination of Boddie and Aigner do not teach the limitations of either claim 10 or claim 11. Applicant respectfully requests the Patent Office withdraw the rejection to claims 10-11 under 35 U.S.C. §103(a).

**C. Rejection of Claims 61-64 as Obvious Over Boddie in view of Aigner and Obvious over Sterman**

Claims 61-64 describe the first and second externally accessible channels for independent claim 1 and independent claim 48. As noted above, externally accessible channels such as a femoral artery, a radial artery and a jugular vein are not described by either Boddie or Aigner which relate to open chest cavity procedures as admitted by the Patent Office. Claims 61-64 thus add structural aspects to the system in that they further define the length dimension of a delivery conduit and/or a collection conduit.

For the above-stated reason and the reasons stated with respect to independent claims 1 and 48, Applicant respectfully requests that that Patent Office withdraw the rejection to claims 61-64 under 35 U.S.C. §103(a).

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN, LLP

Dated: 1/24/06

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Nedy Calderon  
Nedy Calderon

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Date



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ENCLOSURES (check all that apply)		
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Date	January 24, 2006

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